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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/316,313	05/21/1999	RAM PRATAP	U-012254-3	7625
140	7590	10/29/2004	EXAMINER	
LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023			HUANG, EVELYN MEI	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/316,313

**Applicant(s)**

PRATAP ET AL.

**Examiner**

Evelyn Huang

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-18 and 23-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-18 and 23-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. Claims 11-18, 23-32 are pending. Claim 22 has been canceled according to the amendment filed on 8-19-2004.

#### ***Claim Rejections - 35 USC § 112***

2. The rejection for Claims 12, 13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn because the amendment has obviated the rejection.

#### ***Claim Rejections - 35 USC § 102***

3. The rejection for Claims 1-18, 23 under 35 U.S.C. 102(b) as being anticipated by Puri et al. (Am. J. Trop. Med. Hyg., 1989, 41(6): 638-642 ) is withdrawn in view of the amendment limiting the dosage to less than 1.25 mg/kg per day, thereby setting a demarcation from Puri's method of using the curative dose of 1.25 mg/kg per day of CDR1 80/53 to treat malaria in an animal.

#### ***Claim Rejections - 35 USC § 103***

4. The rejection under 35 U.S.C. 103(a) as being unpatentable over Nodiff (5104885) in view of Paliwal et al. (Journal of Chromatography, 1993, 616:155-160) and Puri et al. (Am. J. Trop. Med. Hyg., 1989, 41(6): 638-642 ) is withdrawn for claims 16-18 upon reconsideration in view of Applicant's remarks. The incorporation of the limitation of a single dose has set a demarcation from Puri's curative dose of 1.25 mg/kg or 3.75 mg/kg per day for 7 days.

The rejection, however, is maintained for claims 11-15, 23 for reasons of record. The rejection is applicable to new claim 31. The limitation of less than 1.25 mg/kg per day embraces

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1.249 mg/kg (which is close to Puri's 1.25 mg/kg per day and is within the experimental error), and therefore is still obvious over the prior art of record.

***Claim Rejections - 35 USC § 112(1)***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-18, 23-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 11, 'the amount is less than 1.25 mg/kg of the body weight of the animal per day' is not described in the specification. Only '1.25 mg/kg x 7 days' is described on page 16 of the specification.

Claims 11, 16 and 24, the written description for 'an amount effective to block malarial gametocyte development in the animal whereby to reduce a possibility of gametocyte infectivity to mosquitoes' is not found in the specification.

Claims 25, 31 and 32, the written description for 'wherein the animal is a carrier of mature gametocytes of a Plasmodium species' is not found in the specification.

The rejection is applicable to claims dependent on the above claims.

***Claim Rejections - 35 USC § 112(2)***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 16-18, 24-30, 32 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 16, 24, the dose '5.0 mg/kg' is incomplete. Insertion of 'of the body weight of the animal' after '5.0 mg/kg' would obviate the rejection.
- b. Claim 24,
  - 'within at least a 7 day period' is unclear. 7 days from when?  
Furthermore, the specification recites 'day 8 following their feeding' whereas the Table on page 18 recites 'Day 7'. Clarification is required.
  - 'at least' in 'at least a 7 day period' is open-ended and is therefore indefinite.
- c. Claim 13, it is unclear how the 'amount and manner' of the compound or composition would provide for slow metabolic degradation, since it is the compound itself which has the slow metabolic degradation property. To better define the claim, amending the claim to 'A method according to claim 11, wherein the compound has slow metabolic degradation' is recommended.
- d. Claim 14, it is recommended that 'the compound' be inserted after 'enaminone functionality' to better define the claim.

The rejection is applicable to claims dependent on the above claims.

### ***Conclusion***

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Evelyn Huang  
Primary Examiner  
Art Unit 1625